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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/209,961    12/10/98    WANG    L    9000-0040

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HM22/0720

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MENLO PARK CA 94025

EXAMINER
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SALIMLA

ART UNIT	PAPER NUMBER
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1648

10

DATE MAILED:

07/20/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/209,961

Applicant(s)

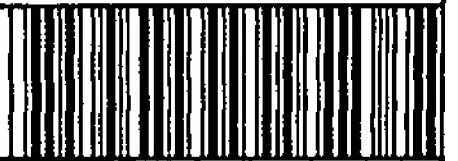
Wang et al

Examiner

ALI R. SALIMI

Group Art Unit

1648



☒ Responsive to communication(s) filed on 5/8/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 7-9, 12-14, 17-19, and 22-24 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 7-9, 12-14, 17-19, and 22-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

#### ***Response to Amendment***

This is a response to the amendment B, paper No.9, filed 5/8/2000. Claims 1-6, 10, 11, 15, 16, 20, 21, and 25-47 have been canceled. Claims 7-9, 12-14, 17-19, and 22-24 are pending before the examiner.

#### ***Claim Rejections - 35 USC § 112***

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 1/21/2000. Applicants argue that the term derived from is well defined in the specification. In addition, applicants argue that the claim in view of the teaching of specification is abundantly clear. Moreover, applicants assert that the examiner is trying to read limitations into the claims and contend that in view of the specification one of ordinary skill in the art would understand the claims. Applicant's argument as part of amendment B, Paper NO. 9, filed 5/8/00 has been considered fully, but they are not persuasive. At the onset applicants are reminded that indeed the claims have been interpreted in light of the specification, however, the limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore,

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when the specification has multiple and varied definition for a phrase it is not clear which definition is intended. For example regarding the definition of "derived from", on page 9 lines 15-17 defines "derived from" as "a sequence which retains the essential properties of the illustrated sequence", however, on page 10, lines 4-6 "derived from" is defined as "a sequence corresponding to the genomic nucleotide sequence." What are the essential properties? What are the corresponding sequences, how are they determined? These are two, and incidently not particularly clear recitation in that, distinct definition of "derived from", wherein by reading the claims and interpreting the claims in light of the specification it is not clear what the applicants intend to claim. Hence, the claims are indefinite when the teaching is unclear and one of ordinary skill in the art can not decipher the clear intended meaning. Moreover, there are many methods and interpretations of the term "derivation", and since there is no uniform understanding of the said term and the claims do not clearly state the intended definition the claims are considered indefinite. In addition, the assertion of "trying to read limitations into the claims" is misplaced. Merely in the interest of compact prosecution and in view of claims being vague and indefinite the examiner was trying to figure out what the claims were intending (emphasis added). Claims 17-19 have broad recitation of "host cell transformed", since the specification refers to wide verity of transformation of cells both in vivo as well as in vitro, there are different patent eligibility weights given to each of the transformations, and by reading the claims one of ordinary skill in the art can not infer which transformation was intended the claims were determined and are still deemed vague and indefinite. The transformation can be interpreted as induction of immune response as

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well as transformation of cells in culture to harvest proteins. Applicants are referred to the abstract where the broad intention of the invention are recited, and in the absence of clear claim language the broadest possible interpretation is given. There are different weights given for the said limitations. Still further, the recitation of "at least about" as stated before is still unclear. Is 75% considered to be at least about? Therefore, the rejection is still deemed proper and is maintained.

***Claim Rejections - 35 USC § 112***

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 1/21/2000. Applicants argue the examiner is reading limitations into the claims which are not present. In addition, applicants argue that the examiner has focused on the "vaccine" embodiment of the present invention.

Applicant's argument as part of amendment B, Paper NO. 9, filed 5/8/00 has been considered fully, but they are not persuasive. As stated previously in view of the compact prosecution the broadest possible interpretations are given to the claimed invention. Furthermore, since the claims do not clearly state the intended recitation, examiner is forced to give the broadest interpretation to the claimed invention. Interestingly enough the applicants' response, see bridging paragraph of page 6 to page 7 recites that "For example the specification teaches production of PCVII proteins using transformed cells and in vivo and ex vivo transfection of a subject's cells", has also read the same limitations into the claims as has the examiner. Applicants have given the broadest interpretation to the claims by reciting that the specification is intended for transformation of cells

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in vivo which would read on gene therapy and vaccine production. In addition, claims are referring to utilization of recombinant vectors and transforming host cells. There is only one inference that can be reasonably made and that is directed to DNA vaccine, or gene therapy, in which the specification is rather deficient in providing adequate teaching. However, as stated before with an unpredictable art such as vaccine production the specification must adequately teach the protective response. Moreover, since the state of the art and examination of the literature does not lend itself to the routine production of vaccine against PCVII, one of ordinary skill in the art would be required to conduct large quantity of non-routine experimentations to enable the full scope of the claimed invention. Still further, since the specification is highly deficient in providing an adequate written description to enable the claims that read on vaccine against PCVII, it is concluded that undue experimentations would be required to enable the invention. The examiner is not aware of a vaccine against PCVII and would welcome any reference that would indicate the induction of protective response in a suitable host against PCVII. Clearly indicating and adding limitations that the transformation is directed to cells in culture only would prevent anyone reading un-intended limitations into the claims. The rejection is respectfully maintained.

***Claim Rejections - 35 USC § 102***

Claims 7-9 are rejected under 35 U.S.C. 102(a) as anticipated Meehan et al (J of Gen. Virology, 1997, vol. 78, pp. 221-227) for reasons of record advanced in the previous Office

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Action mailed 1/21/2000. Applicants argue the cited reference teaches only circovirus type I. In addition, applicants contend that "Two nucleic acid fragments are considered to be "selectively hybridizable" to a PCVII polynucleotide if they are capable of specifically hybridizing to PCVII nucleic acid or variant thereof but not to polynucleotide from other members of circovirus family." Applicant's argument as part of amendment B, Paper NO. 9, filed 5/8/00 has been considered fully, but they are not persuasive. In the first fold the specification is rather vague in its recitation of "specifically or selectively hybridizing" the recitation of so called hybridization appears to be directed to non-stringent conditions, hence, the idea of "selective" hybridization in view of the recited conditions are not only non-selective but rather considered to be rather general hybridization. Because, almost any nucleotide would be hybridized under recited conditions. There is nothing selective about the recited conditions. In addition, the applicants' assertion that the above cited teaching is directed to PCV type I is misplace, since it is well known that PCV I was non pathogenic, however, Meehan et al clearly stated that the PCV produced infectious virus which would mean PCVII and not PCV I. As stated before the cited reference meets the limitations of the identity, fragments, and broad limitations of the claims. In addition, the characteristic inherent to the virus but not articulated still are the property of that virus. There is no evidence to substantiate the assertion made by the applicants that the PCV taught by Meehan et al is not PCVII. The sequence reported by the said reference (GenBank accession number U49186), which incidently was submitted Feb. 1996, meets the limitations of the claims. The rejection is maintained.

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***Claim Rejections - 35 USC § 103***

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meehan et al (J of Gen. Virology, 1997, vol. 78, pp. 221-227) and Vogel et al (Clinical Microbiology Review, 1995, Vol. 8, No. 3, pp. 406-410), for reasons of record advanced in the previous Office Action mailed 1/21/2000. Applicants argue that Meehan et al teach the PCV type I and not PCV type II and they discuss the selective hybridization of the fragments that is not discussed in the reference. In addition, the applicants contend that Vogel et al does not teach circovirus. Applicants' argument as part of amendment B, Paper NO. 9, filed 5/8/00 has been considered fully, but they are not persuasive. In the first fold, applicants are reminded that under USC 103, one should consider that at the time of filing would the invention have been obvious to ordinary skill in the art in view of the teaching available to the skilled artisan and the level of skill and direction provided by the prior teachings. In view of the broad recitation of the claimed invention in the case in hand the answer is a resounding, yes. The reference taught by Meehan et al provided the sequence that meets the limitations of the claims and utilizing well known technique such as transformations of cells and employment of recombinant vectors, well known to those ordinary skill in the art, or vaccine development as taught by Vogel et al, one of ordinary skill in the art at the time of filing would not have anticipated any unexpected results, as none have been provided. Applicants admit in their response that specification does not have to teach what is well known in the art. The transformation of cell culture and hybridization, and producing protein are well known in this art. Meehan et al has already disclosed the sequences



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and transforming the cells with the recited sequences is considered to be routine and obvious in this art, unless the proof of criticality is proven. Hence, in view of the broad limitations of the claims and state of the art the invention is still deemed to be obvious absent unexpected results. The rejection is maintained.

**New grounds of rejection:**

***Claim Rejections - 35 USC § 112***

Claims 7-9, 12-14, 17-19, 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite for recitation of "comprising polynucleotide" the metes and bounds of the comprising is not defined. This limitation is directed to non specified material that is not defined in the specification. This reads on the entire full clone of the PCVII virus. The claim has been interpreted in view of the specification and the specification does not provide for the full virus clone. In addition, the claim is vague and indefinite for recitation of "capable of selectively hybridizing", the term "selectively" is a relative term subject to varied interpretation. The specification discloses a non-stringent condition which is not considered to be "selective." Moreover, the term "capable of" is confusing, what does this mean? The term is a relative term, it

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is not clear whether or not the polynucleotide is hybridizing PCVII or not? This affects the dependent claims.

No claims are allowed.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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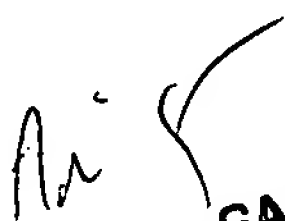
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

7/18/2000

  
ALI R. SALIMI  
PRIMARY EXAMINER